Remarks

Claims 1-46 are pending in the subject application. Claims 5-15, 21-31 and 40-46 have been withdrawn from consideration. By this Amendment, applicants have amended claim 16. Accordingly, claims 1-46 are pending and claims 1-4, 16-20 and 32-39 are under consideration in this application.

Substitute Specification

On page 2 of the August 27, 2002 Office Action, the Examiner noted that the substitute specification filed January 23, 2001 was not entered because it was not accompanied by a statement that the substitute specification contained no new matter in accordance with 37 C.F.R. 1.125(b). The Examiner acknowledged receipt of a version of the specification with markings to show changes made in the substitute specification, as required by 37 C.F.R. 1.121(3)(iii) and 37 C.F.R. 1.125(b).

In reply, applicants hereby state that the substitute specification filed January 23, 2001 contains no new matter. Accordingly, applicants respectfully request that the substitute specification be entered.

Rejection under 35 U.S.C. §112, second paragraph

On page 3 of the August 27, 2002 Office Action, the Examiner rejected claims 16-20 and 32-39 under 35 U.S.C. §112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention.

The Examiner rejected claims 16-20 and 32-39 as allegedly indefinite in their recitation of non-elected subject material. Specifically, the Examiner alleged that independent claim 16 encompasses polymers in addition to the terpolymer of the elected invention encompassing a terpolymer consisting essentially of tyrosine, alanine and lysine randomly polymerized into a polypeptide.

In reply, applicants have amended claim 16 so that it is directed to the elected invention. Applicants point out that claims 17-20 and 32-39 are dependent or secondarily dependent on 16, so claims 17-20 and 32-39 are now directed to the elected invention. Accordingly, applicants respectfully request that the Examiner withdraw the rejection under 35 U.S.C. 112, second paragraph.

Rejection under 35 U.S.C. §102(f)

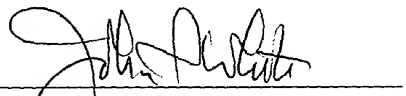
On page 3 of the August 27, 2002 Office Action, the Examiner rejected claims 1-4 under 35 U.S.C. §102(f) alleging that applicants did not invent the claimed subject matter. The Examiner pointed out that page 31 of the substitute specification and page 34 of the originally filed specification disclose that the terpolymer consisting essentially of tyrosine in a mole fraction of about 0.102, alanine in a mole fraction of about 0.542, and lysine in a mole fraction of about 0.353 was obtained from Teva Pharmaceuticals Industry, Ltd. The Examiner also noted that Teva Pharmaceuticals Industry, Ltd. is not an assignee. The Examiner requested clarification to overcome this rejection.

In response, applicants advise the Examiner that Teva Pharmaceutical Industries, Ltd. is a licensee under the subject application, but applicants have not as of the filing of this Amendment completed their investigation. Applicants will advise the Examiner of the relevant facts once they complete their investigation.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

No fee, other than the enclose $410.00 surcharge for the two-month extension of time, is deemed necessary in connection with the filing of this Amendment. However, if any fee is deemed necessary, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,



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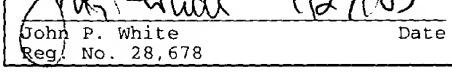
I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner for Patents Washington, D.C. 20231



1/27/03

John P. White Date
Reg. No. 28,678

Version with Markings to Show Changes Made

16. (Amended) A pharmaceutical composition for the treatment of an autoimmune disease, comprising a therapeutically effective amount of a terpolymer comprising three different amino acids randomly polymerized into a polypeptide, and a pharmaceutically acceptable carrier, wherein said three different amino acids are selected from the group of tyrosine, [glutamic acid,] alanine and lysine.